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FISCAL IMPACT STATEMENT

LS 6450

BILL NUMBER: HB 1098

NOTE PREPARED: May 5, 2005

BILL AMENDED: Apr 28, 2005

SUBJECT: Prescription Drugs and Health Professions.

FIRST AUTHOR: Rep. Messer

FIRST SPONSOR: Sen. Dillon

BILL STATUS: Enrolled

FUNDS AFFECTED: X **GENERAL**
DEDICATED
FEDERAL

IMPACT: State

Summary of Legislation: This bill contains the following provisions:

Personal Services & Home Health Services Agencies: This bill establishes a program for the licensing and regulation of personal services agencies. It provides that home health agencies and personal services agencies are approved to provide home health or personal services under certain federal waivers. It provides that home health services include services that are required to be ordered or performed by certain health care professionals. It also increases the home health agency license fee.

The bill requires a personal services agency to comply with employee criminal history check requirements. It provides that a home health agency that operates a personal services agency is not required to obtain a license to operate the personal services agency. The bill also makes operating or advertising an unlicensed personal services agency a Class A misdemeanor.

The bill requires a placement agency to provide the consumer and worker with certain information when a home care services worker is placed in the consumer's home. It allows the State Department of Labor to impose a civil penalty against a placement agency for failing to provide the notice. It also relocates the definition of "attendant care services".

Wholesale Drug Distributions: The bill requires the Board of Pharmacy to establish procedures to ensure that pharmacies may return expired prescription drugs to drug wholesalers and manufacturers. It specifies information that the Board must consider in establishing the procedures. It expands the requirements that must be met by a wholesale drug distributor for eligibility for licensure. It also specifies prohibited acts. The bill

specifies criminal acts related to wholesale drug distribution and legend drugs. It also allows the Board of Pharmacy to establish an electronic pedigree pilot program.

Speech & Language Pathology: The bill amends several definitions concerning speech-language pathology and audiology. It requires licensure of speech-language pathology aides, associates, and assistants. It also amends licensure requirements of speech-language pathologists and audiologists. The bill requires an audiologist to possess a doctorate degree after January 1, 2007, for an initial license. It allows the Professional Standards Board to issue credentials to certain speech language professionals. It also allows certified speech-language pathologists and audiologists who meet certain requirements to be considered to have a National Board of Professional Teaching Standards certification. The bill requires a referral to administer a test of vestibular function. It amends reciprocity licensure requirements for speech language pathologists and audiologists. It requires licenses to be displayed. This bill allows certain state licensure exams to apply to the psychology reciprocity requirements.

The bill also makes conforming changes.

Effective Date: July 1, 2005; January 1, 2006.

Explanation of State Expenditures: *Expired Drug Return Procedures:* The seven-member Board of Pharmacy currently conducts monthly meetings in which the Board should be able to address the requirements of this bill. However, if an additional meeting is needed, the cost associated with mileage reimbursement and per diem would be about \$570 per meeting. Per diem for lay members is \$50.

Speech & Language Pathology: The bill allows the Professional Standards Board to issue licenses to speech-language professionals already licensed by the Speech-Language Pathology and Audiology Board. The fiscal impact of this provision is dependent on the extent to which credentials are sought by the professionals.

The bill also requires speech-language pathologists to register its support personnel with the Health Professions Bureau. The licensing fees imposed by the Board should help offset the cost of creating and maintaining a registry of support personnel.

Personal Services Agency Licensure:

Department of Health - Summary: The total cost of this component of the bill is estimated to be \$278,171 in FY 2006, assuming full operations for three-quarters of the year, and \$290,286 for FY 2007. Fee revenue is estimated to be \$62,500 annually, assuming 250 agencies apply for licensure. The Department of Health estimates the resources required to implement the provisions of this bill based on an assumption that the costs for providing a licensure and regulation program for personal services agencies should be less than those for home health agencies, since personal services agencies' scope of care does not include licensed professionals and the bill specifies that home health agencies will not be required to obtain a separate license to provide personal services as a portion of their business.

The number of personal services agencies that would require licensure has been estimated to be about 250 entities. The Department of Health estimates that they may need up to four additional surveyors and one secretary. It is assumed that these surveyors would be supervised by the existing supervisory staff of the Home Health Care Licensure unit. If a surveyor is hired at the PAT III level, each position would cost approximately \$54,933 in FY 2006, or a total of about \$219,732 in FY 2006 for four surveyors for a full year. If a secretary

is hired at the COMOT III level, the support staff costs would be approximately \$34,647 in FY 2006 for a full year. These estimates include salary, fringe benefits, and health benefits. Total expenditures for all staff (surveyors, support staff, and \$11,316 for a part-time attorney) are estimated at \$265,695 for FY 2006 assuming full staffing for the year. Discussions with the regulatory services staff indicate that the rule promulgation process would be lengthy and hiring probably would not take place until the second quarter of the fiscal year, allowing time to train the staff. Under this assumption, the personal services cost in the first year would be \$199,271.

Other related expenditures would be data base revisions, computers, mileage, and reimbursements for other expenses incurred while traveling. Other operating expenses in the first year would include startup costs for software and data base revisions of \$42,000. The cost for 5 computers at \$2,500 per computer is \$12,500. The actual cost of mileage and related travel expenditures will depend on the amount of traveling required. The Department reports that the average cost for current survey staff is \$6,100 annually. Expenditures for the personal services agency licensing program will come from state funds. There is no comparable federal certification which would allow for federal funds to be claimed.

This bill does not contain an appropriation to fund the personal services agency licensure program.

Budget information on the home health agency survey program was not immediately available. However, it will be included once the information is provided.

Attorney General- The State Department of Health may report to the Attorney General an unlicensed personal services agency. The Attorney General may then seek an injunction or prosecute violations. This provision of the bill could add to the Attorney General's administrative burden, which would depend on individual circumstances.

Department of Labor- The bill requires the Department of Labor to develop a notice for consumers informing them that they may be considered to be an employer of a home care services worker and may be responsible for the payment of local, state, or federal employment taxes, or payment of Social Security and Medicare contributions as well as worker's compensation insurance and other requirements. The bill would allow the Department to investigate alleged violations of the failure to provide notice by a placement agency that places home care services workers in employment. The Department of Labor may incur additional expense if they choose to investigate complaints or audit compliance with this provision. The bill also would allow for the imposition of a civil penalty not to exceed \$1,000 for failure of a placement agency to notify a worker or a consumer at the times specified under the bill.

Wholesale Drug Distributor Licensure: This bill expands the requirements that a wholesale drug distributor must meet in order to be eligible for licensure in Indiana. The Board of Pharmacy already licenses approximately 820 wholesale drug distributors, of which 576 are located out of state. The bill will require national accreditation of wholesale drug distributors. The bill also allows the Board to promulgate rules to accept the accrediting body's conduct of on-site surveys that will meet Indiana licensure requirements. Indiana inspectors will also continue to inspect wholesale distributors located in the state. Currently, the National Association of Boards of Pharmacy (NABPR) has an accreditation process and has recently implemented an inspection service. The cost of the accreditation and inspections is borne by the applicant seeking accreditation and licensure. The Board of Pharmacy has reported that the promulgation of new rules associated with the bill can be accomplished within the level of resources currently available to the Board.

National Criminal History Background Checks- The bill requires the Board to consider the results of national criminal history background checks. Currently, the Board does not require any criminal history checks for wholesale drug distributor licensure. The Indiana State Police charge \$39 for the searches of the FBI national data base; \$24 of the fee goes to the FBI for the data base search, and \$15 is retained by the State Police for deposit in the state General Fund. Fingerprinting is a required component of the national criminal history background check. If the fingerprinting is performed by the State Police, there is no additional charge. If fingerprinting is performed by a local agency, a fingerprinting fee may be assessed depending upon local policy. The bill requires the applicant for the wholesale drug distributor license to bear the expense of the criminal history background checks.

Pedigree Requirements- The bill requires that wholesale drug distributors keep and routinely authenticate legend drug or device pedigrees. The pedigree is a statement or record that may be kept in written or electronic form that records each distribution of a legend drug from the original sale by the manufacturer through the acquisition and sale by each wholesale drug distributor. The pedigree must include specific information outlined in the bill. Pedigrees will be required to be maintained in a written or electronic format after June 30, 2006. This provision is a record-keeping requirement of the wholesale drug distributors and will have a fiscal impact on the Board only to the extent that it affects the rules to be promulgated to implement this bill. The bill also allows the Board to establish a pilot electronic pedigree program within specified parameters after June 30, 2005.

Penalty Provisions- The bill creates two new criminal penalties: (1) legend drug or device deception resulting in death, a Class A felony; and (2) legend drug or device deception, a Class D felony. The bill also expands the existing Class D felony for engaging in wholesale drug distribution without a license to include fraudulent actions concerning record-keeping requirements associated with the wholesale distribution of legend drugs or devices.

A Class A felony is punishable by a prison term ranging from 20 to 50 years depending upon mitigating and aggravating circumstances. A Class D felony is punishable by a prison term ranging from six months to three years or reduction to Class A misdemeanor depending upon mitigating and aggravating circumstances.

The average expenditure to house an adult offender was \$21,514 in FY 2004, ranging from a low of \$16,645 to a high of \$49,281. (This does not include the cost of new construction.) If offenders can be housed in existing facilities with no additional staff, the average cost for medical care, food, and clothing is approximately \$1,825 annually, or \$5 daily, per prisoner. The average length of stay in Department of Correction (DOC) facilities for all Class D felony offenders is approximately ten months. The average length of stay for all Class A felony offenders is approximately 9.1 years.

Explanation of State Revenues: *Personal Services Agency Licensing: License Fee-* The bill requires the State Department of Health to charge a \$250 nonrefundable fee annually for a license to operate a personal services agency. License fee revenue will partially offset the costs of the licensing program. If there are 250 providers as estimated by the Department of Health, the license fees would generate \$62,500 of revenue. Fee revenue is distributed to the General Fund.

Home Health Agency Licensing: License Fee- This bill would allow the maximum fee that the State Department of Health may charge for home health agency licensure to increase from \$200 to \$250 annually. The current home health agency licensing fee is \$100 annually. Any amount of increased fee revenue would depend upon administrative action by the Department of Health.

Penalty Revenue- This bill allows the Attorney General to seek an injunction in a local circuit or superior court or prosecute violations for operating or advertising the operation of an unlicensed personal services agency. The bill also allows the Department of Health to impose a civil penalty of up to \$1,000 for violating provisions of the personal services agency licensing law.

Wholesale Drug Distributor Licensure: Currently, the state license fee for wholesale drug distributors, regardless of location, is \$100 every 2 years. The level of fees that may be charged to cover expenses of the Board of Pharmacy would be dependent upon actions of the Board and the number of distributors continuing licensure. There are currently about 820 licensed distributors. Of these, 244 are located in state, while 576 are located out of state.

Penalty Provisions- If additional court cases occur and fines are collected, revenue to both the Common School Fund and the state General Fund would increase. The maximum fine for a Class D felony and a Class A felony is \$10,000. Criminal fines are deposited in the Common School Fund.

If the case is filed in a circuit, superior, or county court, 70% of the \$120 court fee that is assessed and collected when a guilty verdict is entered would be deposited in the state General Fund. If the case is filed in a city or town court, 55% of the fee would be deposited in the state General Fund.

Speech & Language Pathology: This bill creates licenses for speech-language pathologists who have either an associate degree or bachelor's degree. It also increases the education requirement for the audiologist license from a master's degree to a doctorate. Both of these provisions could have the potential to affect the number of licenses that are applied for. Currently, the Speech-Language Pathology and Audiology Board charges \$150 for speech-language pathologists and audiologists licenses and \$50 for the speech-language pathology aides license. The Board may adopt rules in regards to the licensure of the new speech-language pathologist licenses. The fiscal impact of this bill is dependent on the fees set by the Board and on how the number of license applicants might vary.

The bill also includes an examination, other than the Examination for the Professional Practice of Psychology, that is passed by an applicant from another state as fulfilling the examination requirement for out-of-state applicants. This provision could lead to additional applicants for a psychology license. The Psychology Board charges \$100 for licensure either by examination or by endorsement.

Penalty Provision- If this bill results in additional speech-pathologist licenses being issued, the potential for violation of the law regarding speech-pathologist licensure may be increased. The violation is a Class B misdemeanor. The maximum fine for a Class B misdemeanor is \$1,000.

Explanation of Local Expenditures: *Penalty Provision -* A Class A misdemeanor is punishable by up to one year in jail. A Class B misdemeanor is punishable by up to 180 days in jail. The average daily cost to incarcerate a prisoner in a county jail is approximately \$44.

Explanation of Local Revenues: *Penalty Provision -* If additional court actions occur and a guilty verdict is entered, local governments would receive revenue from the following sources: (1) The county general fund would receive 27% of the \$120 court fee that is assessed in a court of record. Cities and towns maintaining a law enforcement agency that prosecutes at least 50% of its ordinance violations in a court of record may receive 3% of court fees. If the case is filed in a city or town court, 20% of the court fee would be deposited in the county general fund and 25% would be deposited in the city or town general fund. (2) A \$3 fee would be

assessed and, if collected, would be deposited into the county law enforcement continuing education fund. (3)
A \$2 jury fee is assessed and, if collected, would be deposited into the county user fee fund to supplement the compensation of jury members.

State Agencies Affected: Health Professions Bureau, Board of Pharmacy, Speech-Language Pathology and Audiology Board, State Department of Health, Attorney General, Department of Labor, and FSSA/DDARS & OMPP.

Local Agencies Affected: Trial courts, local law enforcement agencies.

Information Sources: Terry Whitson, State Department of Health; Barbara McNutt, Chief Council, Health Professions Bureau, 317-234-1987, “Combating Counterfeit Drugs , A Report of the Food and Drug Administration, at: www.fda.gov/initiatives/counterfeit/report02_04; the National Association of Boards of PharmacyR at: www.nabp.net; Indiana Sheriffs’ Association; Department of Correction.

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